

BEST AVAILABLE COPY

FROM W&C LLP FAXDEPT F#2123548113T#2128197583 (WED) 6.29.05 17:57/ST. 17:52/NO. 4864581419 P 12

1103326-0630

REMARKS

Upon entry of the amendments herein, claims 1, 2 and 27-39 are pending in the application. Claims 1 and 2 have been amended; claims 3-9 and 12-26 have been cancelled; and new claims 27-39 have been added.

As discussed with the Examiner and as addressed in greater detail below, two new compound claims (numbered 27 and 28) have been added. It is Applicants' wish that the formulation, method and process claims, as well as compound claim 18 (now claim 35), depend not only from claims 1 and 2 but from the new compound claims as well. Accordingly, in order to avoid a situation wherein claims do not depend solely from claims preceding them in numerical order, claims 6, 9, 12, 14, 16-18, 20, 24 and 26 have been cancelled and replaced with new claims 29-38, respectively, having proper claim dependencies. Of these, new claims 29-31 further reflect amendments made in response to objections and rejections leveled by the Examiner. As described in greater detail later in this communication, new claims 33 and 34, which are directed to methods employing combinations and which replace claims 16 and 17, further reflect amendments made in anticipation of a possible enablement rejection.

Claims 3-5, 7, 8, 13, 15, 19, 21-23 and 25 have been cancelled without replacement. Many of these no longer fall within the scope of claim 1 in light of the amendments made in

1103326-0630

response to the limitations imposed by the Examiner. Others have been cancelled in response to objections and rejections leveled by the Examiner.

Previously withdrawn claims 2-5, 7, 12, 21 and 22 have been rejoined by the Examiner; Applicants acknowledge with gratitude this action. However, in most instances, "the extent that they depend from or otherwise include all the limitations of claims 1, 6, 9 and 18-20 as noted above" (the Examiner's words) is zero in view of the Examiner's limitations of the scope of various substituents of generic formula (I) of claim 1. In these cases, Applicants have had no choice but to cancel the claims. Thus, of the rejoined claims, only 2 and 12 (the latter now in the form of new claim 31) now remain pending.

In light of the cancellation of claims herein and the replacement of some of them by new claims, claims 1, 2, 29-31, 35 and 36 remain under consideration by the Examiner. Newly added claims 27 and 28 fall within the scope of claim 1, and newly added claim 39 falls within the scope of claim 12 (now claim 31); they thus also merit consideration in this application. Claims 14, 16, 17, 24 and 26 (now claims 32-34, 37 and 38, respectively) remain pending, but withdrawn, at this time.

Applicants further acknowledge with gratitude the Examiner's willingness to discuss, on June 3, 2005, various

1103326-0630

outstanding issues with the undersigned. It had been noted, in the first place, that the previous prior art rejections had all been withdrawn in view of Applicants' last response but that the Examiner had not further extended the search to a broader scope of compounds, and this situation was raised during the discussion. The Examiner indicated that no further search was contemplated during prosecution of the present application. However, a compromise was reached in at least one instance.

The Examiner indicated in the outstanding Office Action that a subgenus of compounds limited, inter alia, to ones wherein R_1 is not heterocyclyl would be allowable. It was pointed out to the Examiner during the discussion that examples 5-21 in the specification all represent compounds wherein R_1 is a heterocyclyl moiety. The Examiner agreed to expansion of the scope of R_1 to include six-membered heterocyclic rings containing a single heteroatom and wherein that heteroatom is nitrogen. Claim 1 has been amended herein to recite the scope of R_1 indicated by the Examiner to be allowable.

The possibility of extending the scope of substituent Y beyond what the Examiner indicated to be allowable was also discussed. In particular, the undersigned requested the inclusion of $C(Z)_2$ in the definition of Y in light of the presence of Examples 17 and 18. However, the Examiner was inflexible in this regard. Accordingly, claim 1 has further

1103326-0630

been amended to limit the scope of substituent Y to O or S. Similarly, the definitions of substituents R₄ and R₆ in claim 1 have been limited by amendment herein to the scope indicated by the Examiner to be allowable. Still further, Applicants have complied with the Examiner's indicated limitations for substituents R₂ and X; in fact, these substituents, particularly R₂, have been greatly reduced in scope beyond the Examiner's requirements.

In view of the various amendments to claim 1, Applicants have met all of the Examiner's requirements with respect to the scope of compounds, and the objections to the considered claims must be withdrawn. Such withdrawal is respectfully requested.

The rejoining of claims 14-17 and 24-26, reciting 1) a kit, 2) a composition containing two active ingredients or 3) both such a composition and a kit, was also discussed with the Examiner. The undersigned pointed out to the Examiner that there is no precedent in the law, or even in MPEP guidelines, for deeming a claim reciting a novel compound to be patentably distinct from a claim reciting that compound in combination with a previously known compound. The Examiner indicated that the exclusion of the combination claims from consideration in the present application may have been arbitrary and inappropriate. He indicated that he would reconsider such claims in the present application with the possibility of rejoining them. The

1103326-0630

Examiner, however, indicated that he would not consider rejoining the claims directed to kits.

Accordingly, it is now Applicants' expectation that claims 14, 16, 17, 24 and 26 (now in the form of new claims 32-34, 37 and 38, respectively) will be rejoined to the other claims currently under consideration. Applicants have amended claims 16 and 17 (as reflected in new claims 33 and 34 replacing them), their presently withdrawn status notwithstanding, in anticipation of the rejoining of claims directed to combinations and in anticipation of the Examiner raising the same "reach-through" enablement issue that he has raised in connection with already rejoined claim 12 (now claim 31). New claim 34 further reflects the amendment of claim 17 whereby it no longer depends from a preceding kit claim; instead, it now depends from formulation claim 32 (formerly claim 14), which claim is among those expected to be rejoined. Claims 15 and 25, directed to kits, have been cancelled without replacement.

Finally, without providing the details of the subject matter, the undersigned broached the subject with the Examiner of the possibility of introducing additional compound claims. The Examiner indicated that, particularly in light of the nonfinality of the present Office Action, he would consider the newly introduced claims. The Examiner further indicated that he would call the undersigned to discuss any perceived problems

1103326-0630

with these claims, should they arise, prior to issuing a formal Office Action. Applicants do not anticipate that such a situation would arise. Support for the new compound claims, 27 and 28, can be found on page 11, lines 1-7 of the specification and in the passage running from page 12, line 6 through page 13, line 11. This description fully supports the newly added claims and there can be no question that these claims merely more particularly describe the compounds encompassed by claim 1 and, therefore, that these claims contain no new subject matter and that consideration of these claims imposes no undue burden on the Examiner. Consideration, entry and allowance of these claims are respectfully requested.

Claim 9 has been rejected as being indefinite. Again, this claim has been replaced by new claim 30. The new claim reflects amendment of the old claim to put it in standard, acceptable form reciting that a therapeutically effective amount of the compound is to be administered.

Claim 12 has been rejected as not being enabled by the specification. The Examiner appears to feel, despite Applicants' previous amendment, that this claim is unacceptably prophetic in nature. Applicants note that many examples exist of such so-called "reach-through" claims being allowed by the Office and found in issued patents. Nonetheless, in the interest of expediting prosecution, the claim has been amended

1103326-0630

by removal of the language in question. The claim as rewritten in the form of new claim 31 is fully enabled by the instant specification and fully addresses the Examiner's concerns.

In connection with the rewriting of claim 12 in the form of new claim 31 as described immediately above, Applicants have also added new method-of-treatment claim 39, directed to the treatment of thrombosis and hypercoagulability. Support for this new claim can be found in the specification on, for example, page 23, lines 9-12.

Claim 13 has been objected to on the grounds that it is a substantial duplicate of claim 1. In the first place, Applicants note that claim 1 is directed to a compound while claim 13 is directed to a pharmaceutical formulation comprising that compound. More properly, the Examiner might have compared claims 9 and 13, both of which recite pharmaceutical formulations. In any event, particularly given the retention of the subject matter of claim 9 in the form of new, parallel claim 30, claim 13 has been cancelled and the Examiner's objection is rendered moot.

Applicants have fully addressed the new issues raised by the Examiner and have amended the claims to reflect the scope of subject matter considered to be allowable by the Examiner. The amendments do not reflect agreement by Applicants that the Examiner's limitation of claimed subject matter is justified;

1103326-0630

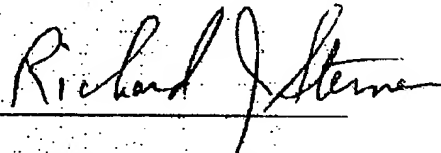
they reflect instead an interest in expediting allowance of this application. Applicants reserve the right to resume prosecution of any and all withdrawn subject matter in one or more divisional applications.

In the meantime, reconsideration and allowance of the present application with pending claims 1, 2 and 27-39 are respectfully requested. Should any other matters require attention prior to allowance, it is requested that the Examiner contact the undersigned.

The Commissioner is hereby authorized to charge any additional fees which may be due for any reason to Deposit Account No. 23-1703.

Dated: June 29, 2005

Respectfully submitted,



Richard J. Sterner
Reg. No. 35,372

Customer Number 007470
(212) 819-8200

Agent's Direct Line:
(212) 819-8783

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.